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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	47865.272600	2442

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,288	WALLEN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 6-22* is/are rejected.

7)☒ Claim(s) *2,4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination

1. Applicant's petition to withdraw abandonment filed 27 December 2005 was approved, and the following is a non-final action rejecting the claimed invention.

Claim Objections

2. Claim 16 is objected to because of the following informalities: It is unclear whether applicant intends to claim the combination of the device of claim 1 along with an injection needle and the fluid transfer device and fluid reservoir as set forth in the claim. Examiner has interpreted the claim to exclude the injection needle and fluid transfer device, since applicant has not positively claimed them as a portion of the claimed invention and has recited them merely as capable of use with the currently claimed mixing device. Appropriate correction is required.

3. Claim 21 is objected to because of the following informalities: It is unclear what, exactly, applicant is claiming as a portion of his device. Applicant claims the device of claim 1, "said device only comprising..." several elements. It is unclear whether applicant is intending to add or subtract limitations from the claim. Examiner has interpreted the claim to incorporate all the limitations of claim 1 and the structural features set forth in claim 21, omitting the restrictions inferred by the word "only." Appropriate correction is required.

4. Claim 22 is objected to because of the following informalities: It is unclear whether applicant intends to claim the combination of the device of claim 1 along with a

drip chamber of an infusion line. Applicant claims that the device is attached to a drip chamber, but does not set forth any limitations with regard to the drip chamber. As such, it is unclear whether applicant is claiming the combination of the claimed device with a drip chamber. Examiner has interpreted the claim to include the combination of the claimed device with the drip chamber, since applicant has recited that the device is attached to the drip chamber. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3, 6-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 5,766,211 to Wood.

In the specification and figures, Richmond discloses the device as claimed by applicant. With regard to claims 1 and 9, Richmond discloses a device that is capable of mixing medical fluids comprising ports that may be used as an inlet port, injection port, and outlet port, respectively (see drawing, as annotated by Examiner, below, FIG 6). The device comprises a first duct 180 that extends between the inlet port and the injection port, and a second duct that extends between the inlet port and the outlet port (see FIG 6). The injection port comprises a hydrophobic, or fluid-proof membrane 182 that is capable of being penetrated by another device (see column 6, lines 18-53). The

device further comprises a first portion that houses the inlet port and the injection port and a second portion that houses the outlet port. Richmond illustrates that the portions are separate through the use of diagonal lines, indicating that the portions may be made of different materials.

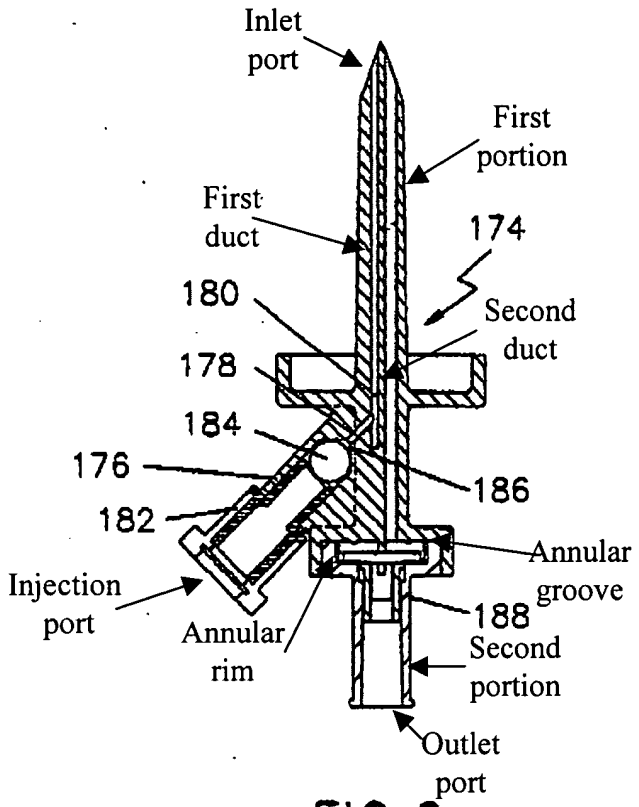


FIG.6.

With regard to applicant's recitation of the type of connection between the first and second portions, such a statement is held by the examiner to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that define the claimed connection. The Richmond device appears to have a friction fit between the first and second portions, which may snap into place. Absent any defining structural characteristics, the Richmond device is capable of operating as claimed by applicant, meeting the limitations of the claim.

Richmond is silent with regard to the materials used to construct the second part of the connector. However, Wood discloses a medical fluid mixing connector that comprises a rigid housing 12 and connecting cylinders 25, 5, and 6, made of an elastic material such as rubber (see Wood, column 5, lines 54-59, column 6, lines 36-45). The elastic material allows for airtight seals between the rigid and non-rigid portions of the device and simplifies connections (see column 6, lines 36-45). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, Richmond illustrates that the connector is composed of two pieces, and Wood discloses a fluid mixing connector with a rigid portion and an elastomeric portion in order to create airtight seals. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the second portion of the Richmond device out of an elastomeric material as disclosed by Wood, in order to create an airtight seal and simplify connections, as taught by Wood (see column 6, lines 36-45).

With regard to claim 3, Richmond illustrates that the second portion of the connector comprises a tube section that extends downward from the connection with the first section, wherein the tube comprises a male luer fitting that is capable of receiving a male luer fitting that displaces the valve, such that the male luer fitting corresponds to the piercing member claimed by applicant. With regard to applicant's recitation of a second retention force, such a statement is held by the examiner to be a statement of the intended use of the device. It has been held that a recitation with

respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that create a second retention force, and it appears that the connection between the female and male luer connectors of the Richmond device is retained by some force, meeting the limitations of the claim.

With regard to claims 6 and 15, Richmond discloses that the outlet port is sealed by a barrier or valve disk 170 that may be deformed by a male luer fitting or piercing element, opening a passage within the disk 170 (see column 6, lines 28-42).

With regard to claim 7, Richmond teaches that the connector comprises a polyethylene or other biocompatible plastic material, but is silent as to the method of molding. The claimed phrase "wherein said first portion has been injection molded from a thermoplastic polymer material" is being treated as a product by process limitation; that is, that the connector is made by injection molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C.102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Richmond is silent as to the process used to mold the connector, it appears that the product in Richmond would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of a thermoplastic polymer material (see column 3, lines 50-57).

With regard to claim 8, Richmond specifically discloses that the first portion of the connector may be made of polyethylene (see column 3, lines 51-55).

With regard to claim 10, Richmond illustrates that the inlet port area comprises a spike 10 that is configured for puncturing the membrane 14 of an IV bag 16 (see column 3, lines 59-67).

With regard to claim 14, Richmond discloses that the outlet port is sealed by valve member 170, but fails to disclose that the valve is integral with and made of the same material as the outlet port (see column 6, lines 28-42). It has been held that forming in one piece an article that was formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, it would have been obvious to a worker in the art to form the barrier disclosed by Richmond integrally with the outlet port, necessarily forming both of the same material, since both modifications are recognized as a matter of obvious design choice.

With regard to claim 16, as interpreted by the Examiner, applicant's claim limitations amount to a recitation of the intended use of the device, since applicant fails to positively set forth the combination of the fluid mixing device and the injection needle with fluid transfer device, reservoir, and membrane. As such, it is the position of the examiner that the connector disclosed by Richmond comprises an outlet port with a

hydrophobic or fluid-proof membrane that is capable of being penetrated by a needle, meeting the limitations of the claims.

With regard to claim 17, applicant's language drawn to the function of the base member is held by the examiner to be a statement of the intended use of the base member. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that are capable of supporting the device when it is in a horizontal position, meeting the limitations of the claims (see column 4, lines 23-33).

With regard to claim 18, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that may be gripped by a user, meeting the limitations of the claim.

With regard to claim 19, Richmond discloses that the device may comprise a cap (not shown, see column 4, lines 23-33).

With regard to claim 20, Richmond illustrates that the connector comprises two portions attached to one another, meeting the limitations of the claim.

With regard to claim 21 as interpreted by the examiner, Richmond discloses that the connector comprises a first portion, second portion, hydrophobic membrane, and a cap or removable hood (see FIG 6, column 3, lines 23-33).

With regard to claim 22 as interpreted by the examiner, Richmond discloses that the connector may be attached to a drip chamber (see column 1, lines 20-25).

7. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 6,142,446 to Leinsing

In the specification and figures, Richmond discloses the device substantially as claimed by applicant (see rejection above) with the exception of a locking or hook member on the connector that engages with a secondary fluid container. Examiner considers the locking member and hook member to be similar in scope such that they both read on the Leinsing disclosure. Leinsing discloses a medical connector with a body 110 and a cannula 122 that may be inserted into a container 138 of medical fluid (see FIG 18). The body comprises claws 118 that correspond to applicant's locking member or hook member. The claws engage the neck of the secondary container to prevent disengagement of the spike from the container (see column 11, lines 31-57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the claws as disclosed by Leinsing to the connector as disclosed by Richmond in order to maintain a connection between the connector and a secondary fluid container, as taught by Leinsing (see column 11, lines 31-57).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 6,146,362 to Turnbull et al.

In the specification and figures, Richmond discloses the device substantially as claimed by applicant (see rejection above) with the exception of a barb member on the connector that engages the interior surface of a fluid transfer port. Turnbull discloses a lfuid transfer device with a fluid transfer spike or key 12 with a retaining ring or barb 50 on the surface of the spike (see column 4, lines 43-65). When the spike is inserted into

a fluid transfer port of an injection port 10, the protrusion engages the interior of the fluid port 10, preventing retraction of the spike 12 from the port (see column 4, lines 43-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a barb member as disclosed by Turnbull to the spkied connector disclosed by Richmond in order to prevent disengagement of the spike from a fluid transfer port, as taught by Turnbull (see column 4, lines 43-65).

Allowable Subject Matter

9. Claims 2, 4, and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the device claimed by applicant.

With regard to claim 2, the prior art fails to disclose or suggest the connector of claim 1 along with the combination of a tapered groove and rim and complimentary snap-fit members. While Richmond discloses a groove and a rim, the reference fails to disclose tapering or a snap-fit member.

With regard to claim 4, the prior art fails to disclose or suggest the device of claim 1 in combination with the tube having a diameter structure as claimed by applicant.

With regard to claim 5, the prior art fails to disclose or suggest the device of claim 1 along with the combination of a tapered groove and rim and complimentary snap-fit

members. While Richmond discloses a groove and a rim, the reference fails to disclose tapering or a snap-fit member.

Response to Arguments

11. Applicant's amendment dated 27 December 2005 has been entered and considered. Applicant's amendment has corrected the 35 USC 112 issue in claim 17. Accordingly, the rejection has been withdrawn.

12. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

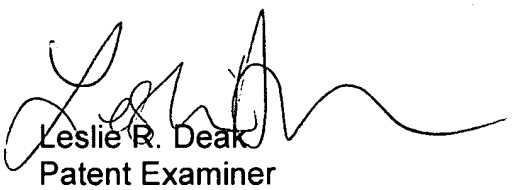
a. US 5,071,413 Utterberg

i. Universal connector

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761